



**IN THE CIRCUIT COURT OF  
MONTGOMERY COUNTY, ALABAMA**

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STATE OF ALABAMA,	)
Plaintiff,	)
v.	)
ABBOTT LABORATORIES, INC.; <i>et al.</i> ,	)
Defendants.	)

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CV - 05 - 219

**FUJISAWA HEALTHCARE, INC. AND FUJISAWA USA, INC.'S  
ANSWER TO PLAINTIFF'S SECOND AMENDED COMPLAINT**

Defendants Fujisawa Healthcare, Inc. and Fujisawa USA, Inc. (collectively referred to as "Fujisawa") for their Answer to Plaintiff's Second Amended Complaint state as follows:

**Preface**

Prior to addressing the specific allegations of the numbered Paragraphs, Fujisawa states the following general objections and responses to the Complaint as a whole. The Complaint contains purported quotations from a number of sources, many of which are unidentified. If any of the quotations originate in documents protected by the attorney-client privilege, the work-product doctrine or the joint-defense privilege, Fujisawa reserves the right to assert such privileges, hereby moves to strike such references and demands return of any such documents that Plaintiff may have in its possession, custody or control. In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

The Complaint also improperly and repetitively refers to Fujisawa and certain other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Fujisawa. It also improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Finally, the Complaint includes terms that are undefined and that are susceptible of different meanings.

Notwithstanding these pleading deficiencies, Fujisawa has attempted to respond to Plaintiff's allegations. To the extent allegations refer to the knowledge, conduct or actions of other defendants or other entities, Fujisawa is generally without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Fujisawa denies those allegations. Fujisawa also denies each and every allegation contained in the Complaint, except as specifically hereinafter admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendoes or speculations that are contained in any averment or in the Complaint as a whole. Moreover, Fujisawa specifically denies any allegations contained in headings, footnotes, any Table of Contents or unnumbered Paragraphs in the Complaint.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

#### INTRODUCTION

1. To the extent that the allegations set forth in Paragraph 1 contain Plaintiff's characterization of the action, no answer is required and none is made. To the extent the allegations set forth conclusions of law, no response is required and none is made. Some allegations in Paragraph 1 contain Plaintiff's generalizations and self-serving conclusions, so to

the extent an answer is deemed required, Fujisawa denies the allegations and demands strict proof thereof.

2. To the extent the allegations of this Paragraph refer to statutory or regulatory programs, the statutes, regulations and other sources regarding those programs speak for themselves. To the extent the allegations in Paragraph 2 describe Plaintiff's status, practices, policies and expenditures, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies those allegations. Other allegations in Paragraph 2 contain Plaintiff's factual generalizations and self-serving conclusions, so to the extent an answer is deemed required, Fujisawa denies the allegations and demands strict proof thereof.

3. To the extent the allegations of this Paragraph refer to requirements or obligations imposed on Plaintiff by statute or regulation, the statutes and regulations speak for themselves. To the extent the allegations in Paragraph 3 describe Plaintiff's status, practices, policies and expenditures, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies those allegations. To the extent that the allegations in Paragraph 3 contain Plaintiff's characterization of the action, no answer is required and none is made. Fujisawa denies the remaining allegations of Paragraph 3 that pertain to it.

4. To the extent the allegations in Paragraph 4 contain Plaintiff's characterization of the action, no answer is required and none is made. Fujisawa denies the remaining allegations of Paragraph 4 that pertain to it.

#### **PARTIES**

5. To the extent the allegations in Paragraph 5 contain Plaintiff's self-characterization, no answer is required and none is made. To the extent the allegations contain Plaintiff's characterization of the action, no answer is required and none is made.

6. To the extent the allegations of Paragraph 6 refer to statutes or regulations, the statutes or regulations speak for themselves. To the extent Paragraph 6 sets forth conclusions of law, no response is required and none is made.

7-42. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 7 through 42, because they refer to the conduct, actions, location or business of defendants other than Fujisawa, and, therefore, Fujisawa denies those allegations. To the extent the allegations of Paragraphs 7 through 42 refer to state or agency statutes, regulations or policies on reimbursement, the statutes, regulations or policies speak for themselves.

The Fujisawa Defendants

43. Fujisawa admits that Fujisawa Healthcare, Inc. is a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois 60015. Fujisawa admits that Fujisawa Healthcare is a wholly-owned subsidiary of Fujisawa Pharmaceutical Co., Ltd., a Japanese corporation.

44. Fujisawa admits that Fujisawa USA was a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois, 60015.

45. Fujisawa admits that Fujisawa Healthcare develops, manufactures, sells and/or distributes prescription products that are reimbursed by state Medicaid agencies in different states across the United States. Fujisawa admits that it developed, manufactured, sold and/or distributed the following products identified in Exhibit A of the Complaint: AmBisome®, Cyclosporine®, Fluphenazine Decanoate, Haloperidol Decanoate, Prograf® and Protopic®. Fujisawa denies any remaining allegations or implications in Paragraph 45.

46-93. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 46 through 93, because they refer to the conduct, actions,

location or business of defendants other than Fujisawa, and, therefore, Fujisawa denies those allegations. To the extent the allegations of Paragraphs 46 through 93 refer to state or agency statutes, regulations or policies on reimbursement, the statutes, regulations or policies speak for themselves.

94. Fujisawa denies the existence of, and its participation in, any "pricing scheme" as alleged in the Complaint. To the extent Paragraph 94 are directed at or describe persons, entities, or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations, and, therefore, denies those allegations. To the extent Paragraph 94 describes Plaintiff's knowledge and abilities, or contains Plaintiff's characterization of the action, no answer is required and none is made. Fujisawa denies the remaining allegations in Paragraph 94.

#### JURISDICTION AND VENUE

95. The allegations in Paragraph 95 set forth conclusions of law. No answer is required. To the extent this paragraph makes implications of fact, Fujisawa denies the allegations of this paragraph.

96. Fujisawa admits that the Court has jurisdiction over Fujisawa. To the extent the allegations of this paragraph reference the conduct of other defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations.

97. To the extent the allegations in Paragraph 97 set forth conclusions of law, no answer is required and none is made. Where the Paragraph references statutes or regulations, those statutes and regulations speak for themselves and are the best evidence of their contents. To the extent allegations in Paragraph 97 contain Plaintiff's description of its own location and

business, Fujisawa is without knowledge or information sufficient to form a belief as to those allegations.

#### FACTUAL BACKGROUND

##### The Alabama Medicaid Program

98-99. The allegations in Paragraphs 98 and 99 describe Plaintiff's own programs and practices, the status of Plaintiff's program, and Plaintiff's budget and expenditures. Upon information and belief, the Alabama Medicaid Program is a state-administered program with federal matching funds that pays for medical care, including prescription drug benefits, for certain Alabama citizens. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations.

100. To the extent the allegations set forth in Paragraph 100 describe Plaintiff's own programs and practices, no answer is required and none is made. To the extent Plaintiff purports to set forth the "common understanding" of the defined terms "Average Wholesale Price," "Wholesale Acquisition Cost" and "Direct Price," Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies those allegations. Fujisawa admits it was aware of Medicaid regulations and procedures. Fujisawa denies the remaining allegations of Paragraph 100.

101. Fujisawa admits the allegations in Paragraph 101 of the Complaint.

102. Paragraph 102 purports to describe the reimbursement methodology of Medicare Part B under federal and Alabama state regulations. The federal reimbursement methodology for Medicare Part B is set forth at 42 C.F.R. § 405.517, which speaks for itself and is the best evidence of its contents. The state Medicaid regulations regarding pharmaceutical services are found in the Alabama Administrative Code at 560-X-16, *et seq.*, and are the best evidence of

Alabama Medicaid's reimbursement methodologies and formulas. Fujisawa admits awareness of Medicaid regulations. Fujisawa denies all remaining allegations of Paragraph 102.

**The Defendants' Reporting of Inflated Pricing Information**

103. To the extent the allegations in Paragraph 103 refer to the knowledge, conduct, opinions or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Further answering Paragraph 103, Fujisawa admits that pharmaceutical industry pricing publications periodically report AWPs for prescription medicines sold in the United States. Fujisawa denies the remaining allegations of Paragraph 103 that pertain to it, and specifically denies knowingly, willfully, wantonly and/or intentionally providing or causing to be provided false and inflated AWP, WAC and/or direct price information.

104. The allegations in Paragraph 104 refer to the knowledge, conduct, practices or actions of Plaintiff and other persons, entities or defendants other than Fujisawa; therefore, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies them.

105. To the extent the allegations in Paragraph 105 refer to the knowledge, conduct, practices or actions of other defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations in Paragraph 105 that pertain to it, and particularly denies that its AWP, WAC and/or direct prices were false, deceptive or misleading.

106. To the extent the allegations in Paragraph 106 refer to the knowledge, conduct, practices or actions of other persons, entities or defendants, Fujisawa is without knowledge or

information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa admits that it knows its own AWP, WAC and/or direct price that it reports to industry reporting services. Fujisawa denies the remaining allegations in Paragraph 106 that pertain to it, and particularly denies that its AWP, WAC and/or direct prices were false and deceptive, or that it participated in any fraudulent scheme described in the Second Amended Complaint.

107. To the extent the allegations in Paragraph 107 refer to the knowledge, conduct, opinions or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations in Paragraph 107 that pertain to Fujisawa.

**Defendants' Marketing of the "Spread"**

108. To the extent the allegations in Paragraph 108 refer to the knowledge, conduct, practices or actions of other defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations in Paragraph 108 that pertain to it.

109. To the extent the allegations in Paragraph 109 refer to the knowledge, conduct, practices or actions of other defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations in Paragraph 109 that pertain to it.

110. To the extent the allegations in Paragraph 110 refer to the knowledge, conduct, practices or actions of other defendants, Fujisawa is without knowledge or information sufficient

to form a belief as to the truth of those allegations and, therefore, denies those allegations.

Fujisawa denies the allegations in Paragraph 110 that pertain to it.

111. To the extent the allegations in Paragraph 111 refer to the knowledge, conduct, practices or actions of other defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

Fujisawa denies the allegations in Paragraph 111 that pertain to it.

**Other Lawsuits, Settlements, Government Investigations, and Criminal Proceedings**

112. Where Paragraph 112 sets forth Plaintiff's characterization of this action, no answer is required, and none is made. Fujisawa admits to the existence of similar meritless and ill-informed claims in various other states and a consolidated multi-district action in Massachusetts. Fujisawa objects to and denies any implication from Plaintiff's reference to a "family of Defendants." Fujisawa further denies involvement in any drug pricing fraud scheme. To the extent the allegations in Paragraph 112 refer to the knowledge, conduct, practices or actions of other defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies them. Fujisawa denies the allegations in Paragraph 112 that pertain to it.

113. To the extent the allegations in Paragraph 113 purport to characterize published opinions and other public record documents regarding litigation related to published AWPs, the published opinions and public records speak for themselves and are the best evidence of the nature of those actions and the content of those records. Fujisawa denies the factual allegations that Plaintiff has derived from Plaintiff's self-serving inferences and conclusions from public record documents, and Fujisawa denies all remaining allegations in Paragraph 113.

114. By information and belief, Fujisawa admits that federal criminal actions have been instituted against some of the other defendants that Plaintiff has named in this action. To the extent the allegations in Paragraph 114 purport to characterize the pleas and/or settlements of those defendants, Fujisawa is without knowledge or information to form a belief as to the truth of Plaintiff's allegations and, therefore, denies those allegations.

115. To the extent the allegations in Paragraph 115 refer to the conduct of other entities or defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations. Fujisawa denies all other allegations of this paragraph.

116. The allegations in Paragraph 116 refer to the conduct of other entities or defendants. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations.

117. The allegations in Paragraph 117 refer to the conduct of other entities or defendants. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations.

118. The allegations in Paragraph 118 refer to the conduct of other entities or defendants. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations.

119. The allegations in Paragraph 119 refer to the conduct of other entities or defendants. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations.

120. The allegations in Paragraph 120 refer to the conduct of other entities or defendants. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations.

121. To the extent Paragraph 121 contains allegations that purport to quantify Plaintiff's losses, no answer is required and none is made. Fujisawa is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations.

122. To the extent the allegations in Paragraph 122 refer to the conduct of other entities or defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations. Fujisawa denies the statements attributed to Representative Pete Stark insofar as the source of the quoted materials is unidentified. Fujisawa denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion of Mr. Stark, the General Accounting Office, Health and Human Services or the Department of Justice, and denies that such are applicable to Fujisawa.

123. To the extent the allegations in Paragraph 123 and its chart refer to the conduct of other entities or defendants, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations. To the extent the allegations in the paragraph and its chart purport to set forth information published by DOJ or industry pricing publications, the original publications speak for themselves and are the best evidence of their content. Fujisawa admits that it is aware of AWPs published in industry pricing publications. Fujisawa denies the remaining allegations of Paragraph 123.

124. The allegations in Paragraph 124 contain Plaintiff's self-serving summary of its foregoing allegations and self-serving characterization of Plaintiff's own knowledge. Accordingly, no answer is required, and none is made. To the extent an answer is deemed to be required, Fujisawa denies the allegations and strict proof is demanded thereof.

125. The allegations in Paragraph 125 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required, and none is made. To the extent an

answer is deemed to be required, Fujisawa denies the allegations and strict proof is demanded thereof.

126. The allegations in Paragraph 126 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required, and none is made. To the extent an answer is deemed to be required, Fujisawa denies the allegations and strict proof is demanded thereof.

### CLAIMS

#### COUNT ONE – FRAUDULENT MISREPRESENTATION

127. In answering Paragraph 127, Fujisawa hereby repeats, incorporates by reference and reasserts its answers set forth in Paragraphs 1 through 126 to each and every corresponding allegation in Plaintiff's Complaint.

128. To the extent the allegations in Paragraph 128 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 128 to the extent they are alleged as to Fujisawa.

129. To the extent Paragraph 129 sets forth conclusions of law, no answer is required and none is made. To the extent the allegations in Paragraph 129 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 129 to the extent they are alleged as to Fujisawa.

130. To the extent the allegations in Paragraph 130 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 130 to the extent they are alleged as to Fujisawa.

**COUNT TWO - FRAUDULENT SUPPRESSION**

131. In answering Paragraph 131, Fujisawa hereby repeats, incorporates by reference and reasserts its answers set forth in Paragraphs 1 through 130 to each and every corresponding allegation in Plaintiff's Complaint.

140.<sup>1</sup> To the extent Paragraph 140 sets forth conclusions of law, no answer is required and none is made. To the extent the allegations in Paragraph 140 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the remaining allegations of Paragraph 140 to the extent they are alleged as to Fujisawa.

141. To the extent Paragraph 141 sets forth conclusions of law, no answer is required and none is made. To the extent the allegations in Paragraph 141 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and,

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<sup>1</sup> Plaintiff's Second Amended Complaint does not contain paragraphs numbered 132 through 139. Accordingly, this Answer also omits those paragraph numbers so that Fujisawa's responses coincide with the paragraphs of the Complaint.

therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 141 to the extent they are alleged as to Fujisawa.

142. To the extent the allegations in Paragraph 142 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 142 to the extent they are alleged as to Fujisawa.

**COUNT THREE- WANTONNESS**

143. In answering Paragraph 143, Fujisawa hereby repeats, incorporates by reference and reasserts its answers set forth in Paragraphs 1 through 142 to each and every corresponding allegation in Plaintiff's Complaint.

144. To the extent the allegations in Paragraph 144 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 144 to the extent they are alleged as to Fujisawa.

145. To the extent that Paragraph 145 contains self-serving conclusory allegations regarding Plaintiff's alleged injury, no answer is required, and none is made. To the extent the allegations in Paragraph 145 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 145 to the extent they are alleged as to Fujisawa.

146. To the extent the allegations in Paragraph 146 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 146 to the extent they are alleged as to Fujisawa.

147. To the extent the allegations in Paragraph 147 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 147 to the extent they are alleged as to Fujisawa.

**COUNT FOUR – UNJUST ENRICHMENT**

148. In answering Paragraph 148, Fujisawa hereby repeats, incorporates by reference and reasserts its answers set forth in Paragraphs 1 through 147 to each and every corresponding allegation in Plaintiff's Complaint.

149. To the extent the allegations in Paragraph 149 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 149 to the extent they pertain to Fujisawa.

150. To the extent the allegations in Paragraph 150 refer to the knowledge, conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 150 to the extent they are alleged

as to Fujisawa, particularly that Fujisawa improperly inflated rates by using false AWPs, WACs and direct prices.

151. To the extent the allegations in Paragraph 151 refer to the conduct or actions of persons, entities or defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Fujisawa denies the allegations of Paragraph 151 to the extent they are alleged as to Fujisawa.

152. To the extent Paragraph 152 refers to the knowledge of defendants other than Fujisawa, Fujisawa is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations of Paragraph 152 are alleged as to Fujisawa, Fujisawa denies the allegations.

Fujisawa further denies that Plaintiff is entitled to a judgment or any other relief requested in Plaintiff's section entitled "Prayer for Relief" and its unnumbered "Wherefore" paragraphs following Paragraph 152 of the Complaint, or to any relief from Fujisawa. Fujisawa demands strict proof of each element of all claims, and of all claimed injuries and damages.

**FUJISAWA HEALTHCARE, INC. AND FUJISAWA USA, INC.'S  
AFFIRMATIVE DEFENSES**

**First Defense**

The Second Amended Complaint violates Rule 20 of the Alabama Rules of Civil Procedure in that it improperly joins separate and distinct claims against numerous defendants that do not arise out of the same transaction, occurrence, or series of transactions or occurrences.

**Second Defense**

Plaintiff fails to state a claim against Fujisawa upon which relief may be granted.

**Third Defense**

Some or all of Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**Fourth Defense**

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Fujisawa as alleged in the Complaint.

**Fifth Defense**

To the extent Plaintiff or any of its citizens for whom it is seeking relief obtains recovery in any other case predicated on the same factual allegations, it is barred from seeking recovery against Fujisawa based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel and the prohibition on double recovery for the same injury.

**Sixth Defense**

Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Alabama.

**Seventh Defense**

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff or any of its citizens for whom it is seeking relief has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

**Eighth Defense**

Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

**Ninth Defense**

Any and all actions taken by Fujisawa with respect to any of the matters alleged in the Second Amended Complaint were taken in good faith and in accordance with established industry practice.

**Tenth Defense**

Plaintiff's claims are preempted, in whole or in part, by federal law, including, without limitation, the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

**Eleventh Defense**

Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

**Twelfth Defense**

Plaintiff's claims against Fujisawa are barred because Fujisawa has complied with all applicable regulations of the federal and state governments.

**Thirteenth Defense**

Plaintiff's claims against Fujisawa are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

**Fourteenth Defense**

Plaintiff's claims are barred, in whole or in part, because they violate Fujisawa's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Alabama, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Fifteenth Defense**

Fujisawa's statements or actions were not the proximate cause or cause in fact of any injury or alleged loss.

**Sixteenth Defense**

Plaintiff fails to state with particularity facts to support the allegations against Fujisawa.

**Seventeenth Defense**

Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit.

**Eighteenth Defense**

Plaintiff's claims against Fujisawa are barred, in whole or in part, because Fujisawa did not make any false statements to Plaintiff or any of the citizens for whom Plaintiff is seeking relief. As to any statement asserted against Fujisawa that Plaintiff alleges to be false or misleading, Fujisawa had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Nineteenth Defense**

Plaintiff's claims against Fujisawa are barred because Fujisawa did not directly or indirectly engage in any conduct in violation of state or federal law.

**Twentieth Defense**

To the extent that Plaintiff seeks equitable relief against Fujisawa, Plaintiff is not entitled to such relief because there is an adequate remedy at law.

**Twenty-first Defense**

Plaintiff did not rely on the allegedly fraudulent statements or conduct of Fujisawa.

**Twenty-second Defense**

Plaintiff's claims against Fujisawa for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**Twenty-third Defense**

Some or all of Plaintiff's claims for injunctive relief against Fujisawa are barred by the doctrines of *in pari delicto*, unclean hands and/or estoppel.

**Twenty-fourth Defense**

Some or all of Plaintiff's claims against Fujisawa arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligations to properly establish appropriate reimbursement rates.

**Twenty-fifth Defense**

Plaintiff's claims against Fujisawa are barred, in whole or in part, due to its failure to join indispensable parties.

**Twenty-sixth Defense**

Plaintiff's claims against Fujisawa are barred, in whole or in part, because it suffered no damages as a result of the matters alleged in the Complaint.

**Twenty-seventh Defense**

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of third parties.

**Twenty-eighth Defense**

Plaintiff's claims against Fujisawa for damages are barred, in whole or in part, because:

- (1) Plaintiff failed to mitigate its damages, and that failure to mitigate damages should

proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Fujisawa; (2) Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Second Amended Complaint; (3) by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by Fujisawa after the filing of Plaintiff's original Complaint; and (4) Plaintiff's claims are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Twenty-ninth Defense**

Fujisawa is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

**Thirtieth Defense**

The applicable statutory ceilings on recoverable damages must limit any damages recovered by Plaintiff from Fujisawa.

**Thirty-first Defense**

Plaintiff fails to allege facts or a cause of action against Fujisawa sufficient to support a claim for compensatory damages, attorneys' fees and/or legal fees, punitive damages, costs, or any other relief.

**Thirty-second Defense**

To the extent Plaintiff seeks punitive damages, such punitive damages claims against Fujisawa: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the First Amended Complaint are legally insufficient to support a claim for punitive damages against Fujisawa; (3) cannot be sustained because laws regarding the standards for determining liability

for and the amount of punitive damages fail to give Fujisawa prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Fujisawa's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Alabama; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Fujisawa's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and applicable state laws of Alabama; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Fujisawa for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Fujisawa's medicines, would constitute impermissible multiple punishments for the same wrong in violation of Fujisawa's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law and statutory law of Alabama; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Fujisawa's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and public policies of Alabama; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Fujisawa the same protections that are accorded to all criminal defendants, including the protection against

unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Fujisawa's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law and public policies of Alabama.

**Thirty-third Defense**

To the extent Plaintiff seeks punitive damages against Fujisawa, such a claim cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation, the residence, wealth, and corporate status of Fujisawa; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Fujisawa's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law and public policies of Alabama.

**Thirty-fourth Defense**

To the extent Plaintiff seeks punitive damages against Fujisawa, such a claim cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Fujisawa's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Fujisawa's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law and public policies of Alabama.

**Thirty-fifth Defense**

Plaintiffs' Complaint seeks to make Fujisawa liable for punitive damages. The United States Supreme Court reversed the Alabama Supreme Court in the case styled *BMW of North America, Inc. v. Gore*, 116 S. Ct. 1589 (1996), on the issue of punitive damages. Fujisawa adopts by reference the defenses, criteria, limitations, and standards mandated by the United States Supreme Court decision in that case and in *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), and any subsequent applicable decisions.

**Thirty-sixth Defense**

Fujisawa affirmatively pleads that any damages that Plaintiff may recover in this case from Fujisawa must be limited by the applicable statutory ceilings on recoverable damages, including without limitation, Alabama Code 6-11-21, as amended, and in the spirit of the Alabama Supreme Court's decision in *Oliver v. Towns*, 738 So. 2d 798 (Ala. 1999).

**Thirty-seventh Defense**

Fujisawa adopts by reference any additional applicable defense pled by any other defendant in this case, not otherwise pled herein, except to the extent that such a defense is inconsistent with Fujisawa's defenses pleaded in this Answer.

**Thirty-eighth Defense**

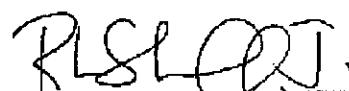
Fujisawa hereby gives notice that it intends to rely upon any other and additional defense(s) that is now or may become available or appear during or as a result of the discovery proceedings in this action and hereby reserves its right to amend its Answer to assert such defense.

WHEREFORE, Fujisawa respectfully demands judgment dismissing the Second Amended Complaint in its entirety and awarding it the costs and disbursements of this action, as well as such other and further relief as this Court deems just and proper.

Respectfully Submitted,

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Attorneys for Defendants Fujisawa  
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Dated: January 30, 2006

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of Fujisawa Healthcare, Inc. and Fujisawa USA, Inc.'s Answer to Plaintiff's Second Amended Complaint was delivered to all counsel of record via electronic service by sending on January 30, 2006 a copy to Lexis Nexis File & Serve for posting and notification to all parties.

*RLS/EPJ*  
OF COUNSEL